

## REMARKS

Applicants have carefully reviewed the Office Action dated September 12, 2001. With this Amendment, Applicants have amended claim 3. Claims 1-9, 11-15, and 21 remain pending in this application.

Claims 1-6, 12, 13, 15, and 21 are rejected under 35 U.S.C. §102(b) as being anticipated by Lee in U.S. Patent No. 5,125,904. As to claims 1-2, Applicants' claim 1 recites "means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen". As described at page 8, lines 15-19, one such means for compressing the valve sleeve pinches the valve sleeve, substantially closing the valve sleeve and restricting fluid flow therethrough. Applicants' specification also discloses that means for compressing the valve may also include a pinch member and/or a pinch member having a recess, please see page 7, lines 10-20. The recess is designed to allow a guidewire or catheter to remain within the closed valve sleeve. Thus, Applicants' means for compressing the valve can seal the valve by pinching the sleeve in either the presence or the absence of a catheter or guidewire.

In contrast, Lee discloses a hemostatic valve that includes a seal membrane 22 that forms a seal between the valve and a catheter or lead. The Examiner asserts that the seal membrane 22 is the means for compressing the valve sleeve recited in Applicants' claim. This is believed incorrect. As stated by Lee, the seal membrane is simply a self-sealing membrane. Thus, fluid flow is restricted between the catheter and the valve by the membrane. Lee fails to disclose means for compressing the valve sleeve in order to seal the valve, either in the presence or the absence of a catheter. Applicants respectfully submit that these remarks overcome the rejection under 35 U.S.C. §102(b) and that claim 1 is in condition for allowance. Because claim 2 depends from 1, it is allowable based on these remarks and because it contains elements to

distinguish it from the prior art.

As to claims 3-6, Applicants respond to this rejection by amending claim 3 to recite that means for reversibly restricting fluid flow includes a valve sleeve and means for compressing the valve sleeve. For the reasons stated above, Applicants respectfully submit that Lee does not disclose means for compressing the valve sleeve. Based upon this amendment, Applicants respectfully submit that claim 3 is in condition for allowance. Because claims 4-6 depend from 3, they are allowable based on these remarks and because they contain elements to distinguish them from the prior art.

As to claims 12-13, Applicants similarly respond to this rejection by stating that claim 12 recites a valve sleeve and a pinch member for pinching the valve sleeve, which is not disclosed by Lee. Applicants respectfully submit that these remarks overcome the rejection and that claim 12 is in condition for allowance. Because claim 13 depends from 12, it is allowable based on these remarks and because it contains elements to distinguish it from the prior art.

As to claims 15 and 21, Applicants similarly respond to this rejection by stating that claim 15 recites a flexible sleeve and the sleeve and sleeve lumen are constricted between the body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position, which is not disclosed by Lee. Applicants respectfully submit that these remarks overcome the rejection and that claim 15 is in condition for allowance. Because claim 21 depends from 15, it is allowable based on these remarks and because it contains elements to distinguish it from the prior art.

Claims 1-9, 11-15, and 21 are rejected under 35 U.S.C. §102(e) as being anticipated by Heck in U.S. Patent No. 6,083,207. As described above in regard to Lee, Heck similarly discloses a hemostatic valve adapted to seal onto a catheter or a lead. Heck does not disclose

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen as recited in Applicants' claim 1. In addition, Applicants' independent claims 3 (as amended), 12, and 15 recite similarly distinct element and are believed to be allowable. Because claim 2 depends from 1, claims 4-9 and 11 depend from 3, claims 13-14 depend from 12, and claim 21 depends from 15, they are allowable based on these remarks and because they contain elements to distinguish them from the prior art.


Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance; issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Michael S.H. Chu et al.

By their attorney,

Date: 12/12/01



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**Version with Markings to Show Changes Made**

**In the Claims:**

Claim 3 has been amended as follows:

3. (Once Amended) A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow include a valve sleeve and means for compressing said valve sleeve;

means for breaking apart said fluid flow restricting means responsive to applied force;  
and

means for admitting a catheter distal end into said valve.